REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated March 23, 2004 are respectfully requested.

I. Amendments

Applicants have amended the specification in accord with M.P.E.P. § 2163.07(b) to include text from column 3, lines 50-52; and column 7, lines 51-67 of the parent 5,728,143 patent, which was properly incorporated by reference.

Claims 53 and 57 are amended to recite that the electrodes are deployed from the distal end of the elongated delivery device. Support for this amendment can be found, for example, in original claim 12 and Figure 11.

New claims 74 and 75 find support on page 15, lines 1-4.

The drawings are amended in accord with M.P.E.P. § 2163.07(b) to include Figure 3 (now Figure 11) of the '143 patent, which was properly incorporated by reference.

By these amendments, no new subject matter has been added.

II. Oath/Declaration

The Examiner's attention is drawn to the decision mailed June 2, 2004 granting Applicant's petitions under 37 C.F.R. §1.183 to waive 37 C.F.R. §1.48 (a)(3), under 37 C.F.R. §1.183 to waive 37 C.F.R. §1.64 and §1.67, and under 37 C.F.R. §1.48(a). Accordingly, Applicants submit that there is a properly executed Declaration on the file.

III. Rejections under 35 U.S.C. §103

Claims 53-56 were rejected under 35 U.S.C. §103 as allegedly obvious over Stadelmayr (DE 2,124,684) in view of Edwards et al. (U.S. Patent No. 5,370,675).

Claims 57-62 and 64-73 were rejected under 35 U.S.C. §103 as allegedly obvious over Edwards et al. in view of Stadelmayr.

These rejections are respectfully traversed.

A. The Present Invention

The present invention describes a method for ablating tissue. The method, according to claim 53 comprises advancing a tissue ablation apparatus comprising an elongated delivery device and at least one RF electrode that is pre-shaped to assume a curved shape and define an ablation volume when deployed. The distal end of the delivery device is positioned in or adjacent the tumorous tissue and the electrodes are deployed from the distalmost end of the elongated delivery device. Energy is delivered the selected tissue site through the electrodes to ablate the tissue. The temperature is monitored using at least one sensor positioned on the (at least one) RF electrode, and delivery of the energy is modulated when the temperature reaches a predetermined limit.

The method, according to claim 57, comprises positioning an ablation apparatus comprising an elongated delivery device and a plurality of electrodes that are pre-shaped to assume a curved shape and define an ablation volume when deployed. The apparatus is positioned to place the distal tip of the delivery device in or adjacent the tissue mass. The plurality of electrodes are deployed from the distalmost end of the elongated delivery device to define an ablation volume that includes the tissue mass. An ablating current is applied to the deployed electrodes and the tissue mass contained within the defined volume is ablated. A characteristic of the tissue mass is monitored using at least one sensor positioned on at least one of the electrodes as the tissue mass is being ablated. The extent of ablation is controlled in response to the characteristic detécted.

B. The Prior Art

STADELMAYR discloses an insertion electrode for biomedical uses which enables larger objects, such as electrodes of massaging heads, to be inserted into body tissue or body cavities. The electrodes find use as antennae, heating for shortwave therapy, and cauterization, as well as operation instruments, for ionophoresis for the destruction of tumors and for mechanical vibrators for loosening of tissue and the destruction of tumors.

EDWARDS ET AL. describe a medical probe device for treatment of the hyperplastic tissues of the prostate to treat benign prostatic hyperplasia. The probe comprises a catheter having a stylet guide housing for directing a stylet out of the catheter and into the tissue. The catheter is advanced through ducts adjacent to the desired treatment area. The stylet is advanced out of the catheter to penetrate the urethral wall to penetrate the prostate.

C. Analysis

According to the MPEP § 2143, one of the three basic criteria to establish a prima facie case of obviousness is that the prior art references (or references when combined) must teach or suggest all the claim limitations.

The combinations of Stadelmayr in view of Edwards et al. and Edwards in view of Stadelmayr each fail to show or suggest electrodes deployed from the distalmost end of the elongated delivery device as in the present invention.

The electrodes of Stadelmayr extend from behind a tip ("Spitze" 4, 12, and 22 - see Figures 1a and 1b, the cross-sections in Figures 5a and 5b, Figure 2 and the corresponding cross-section in Figure 7) and not from the distalmost end of the electrode. Nor would one modify Stadelmayr to include deployment from the distal end as the end of the device is specifically shaped in order to provide a "puncture electrode" (see page 1, lines 13-18 of the translation).

Nor does Edwards et al. teach electrodes deployed from the distalmost end of the elongated delivery device. As seen in Figure 4, the stylet is deployed from a stylet guide in the side of the catheter in order to penetrate the urethral wall and access the prostate for treatment. Nor would one modify the device of Edwards et al. to deploy the stylet from the distalmost end of the catheter as (i) the distalmost end of the catheter is not penetrating so as to minimize damage to the urethra as the catheter is deployed, and (ii) the stylet deploys from the side of the catheter due to the location of the prostate.

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Thus, neither of the references, alone or in combination, show the claimed feature of deploying the electrodes from the distalmost end of the elongated delivery device.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

Date: (July 13, 2004)

Sacqueline F. Mahoney Registration No. 48,390

acqueling & Maharey

Correspondence Address:

Customer No. 22918 (650) 838-4300